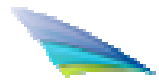




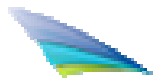
Release 4 Overview
for
OTC Working Group

15 December 2008



Agenda

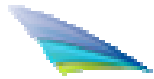
- Guidance Overview
- Corporate Overview
- Solutions Overview
- Solution Demonstration
- Questions and Answers



Guidance Overview

■ Life cycle

- ◆ Human Prescription Labeling (October 31st 2005)
- ◆ Packaging update (November 2005)
- ◆ Physicians Labeling Rule (June 2006)
- ◆ Electronic Registration and Listing Pilot (July 2008)
- ◆ Biologics (October 2008)
- ◆ Electronic Registration and Listing Deadline (June 2009)
- ◆ Proposed – Devices 20??



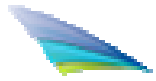
Corporate Overview

■ Life Sciences IT Consulting Practice

- ◆ Located in Tampa, Florida
- ◆ Big 4 consulting background
 - > Technically superior solutions
 - > Intuitive approach
 - > Proven processes

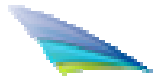
■ SPL Partnership Company

- ◆ “This is what we do”
 - > 500+ successful SPL product submissions to the FDA
 - > Services provided to multiple top pharmaceutical organizations
 - > Serving on the SPL Leadership team / SPL Working groups
 - Entire organization works specifically on SPL in some capacity
 - Business process integration
 - Solution development
 - Management
 - Executives
 - > Always aware of the direction of the guidance
- ◆ No outsourcing – US based



Solutions Overview

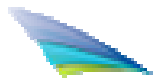
- What should an optimal solution provide?
 - ◆ Would not introduce...
 - Process change
 - Hardware
 - Software
 - Additional resource allocation
 - Additional risk
 - Compliance lag
 - Data entry errors
 - 100% FDA and Schema rules validation



Solutions Overview (continued)

■ What should an optimal solution provide? (continued)

- ◆ **Additional value** outside of SPL via...
 - Process management functionality
 - Audit trail
 - Measureable statistics
 - Continual functionality updates
 - Role based security
 - Global access - 24/7/365
 - Unlimited users
 - Real time validation
 - Data entry mistake prevention
 - Multiple rendition creation (for uses downstream)
 - Word
 - PDF
 - SPL
 - XHTML

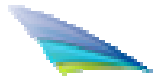


Solutions Overview (continued)

■ What should an optimal solution provide? (continued)

◆ It should be....

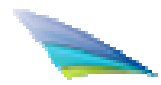
- Intuitive
- Easy to use
- Easy to learn
- Updated for day one compliance (no lag)
- Backed by a proven SPL focused company
- US based
- Hosted at professional SAS 70 audited locations
- Does not impose additional burden to your IT organization
- Includes infrastructure requirements
 - Backups
 - Failover
 - Data encryption
 - Update strategy
 - Software interoperability



Solutions Overview (continued)

■ What should an optimal solution provide? (continued)

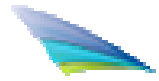
- ◆ A “**Unified Solution**” that is.....
 - In production now
 - You could use today
 - Provides more value than just SPL compliance
 - A strategic tool for your organization
 - Low start up costs
 - Flexible
 - Based on your needs provides
 - Outsourcing
 - Independent use



Solutions Overview (continued)

Would this be valuable to your organization?

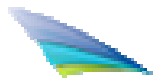




Solutions Overview

■ Two Models

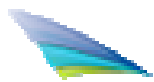
- ◆ In-house
- ◆ Outsourcing



Solutions Overview (continued)

■ In-house

- Home Grown Application
 - Entail
 - Requirements & Design
 - Development
 - Testing
 - Integration
 - Maintenance
 - Expensive to develop and maintain
- Purchased Application
 - Two imperfect approaches
 - File based approach
 - File based approach with repository integration
 - Neither meets the optimal solution approach we defined earlier
 - Would require: hardware, software, process change, additional resources
 - Would not provide: process management, audit trail, statistics, role based security, global access, mistake prevention
 - Etc. etc. etc.



Solutions Overview (continued)

■ File Based Application Example



Initial Setup

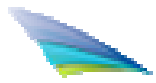
Manufacturing and
Packaging Site for
25 Unique Products

**You would have to enter data
for all 25!**

**...and you would have to
make sure the data is
entered exactly the same
FOR ALL OF THEM!**

25 Unique Product Inserts





Solutions Overview (continued)

■ File Based Application Example (continued)



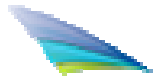
Manufacturing and
Packaging Site for
25 Unique Products

**Data Change
(DUNS or Name)**

**You would have to remember
to update all 25!
...and you would have to
make sure the data is
entered exactly the same
FOR ALL OF THEM!**

25 Unique Product Inserts





Solutions Overview (continued)

■ File Based Application Example (continued)

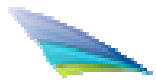
⚠ What's the Likelihood?

⚠ Why leave it to chance?

⚠ If it does happen -

⚠ How will you remember to update all of the documents?

⚠ A central repository and unified solution reduces this risk!



Solutions Overview (continued)

■ Outsourcing (Intagras offerings)

✓ Full Outsourcing

- ✓ All tasks are done for you

✓ Configuration

- ✓ NDC Labeler Codes

- ✓ Establishment Registration

- ✓ Product Data

- ✓ Listing Submission

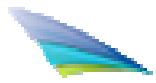
- ✓ Your processes stay the same

✓ You're paying for

- ✓ Expertise

- ✓ Experience

- ✓ Flexibility



Solutions Overview (continued)

■ Outsourcing (Continued)

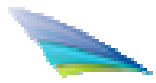
✓ SaaS (Software as a Service)

✓ Does not introduce...

- Process change
- Hardware
- Software
- Additional resource allocation

⚠ Additional risk

- ⚠ Compliance lag
- ⚠ Data entry errors
- ⚠ FDA and Schema rules validation



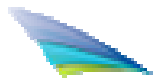
Solutions Overview (continued)

■ Outsourcing (Continued)

✓ SaaS (Software as a Service)

✓ Provides...

- ✓ Process management functionality
- ✓ Audit trail
- ✓ Measureable statistics
- ✓ Continual functionality
- ✓ Role based security
- ✓ Global access - 24/7/365
- ✓ Unlimited users
- ✓ Real time validation
- ✓ Data entry mistake prevention
- ✓ Multiple rendition creation (for uses downstream)
 - ✓ Word
 - ✓ PDF
 - ✓ SPL
 - ✓ XHTML

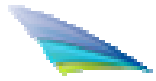


Solutions Overview (continued)

■ Outsourcing (Continued)

✓ SaaS (Software as a Service)

- ✓ Intuitive
- ✓ Easy to use
- ✓ Easy to learn
- ✓ Updated for day one compliance (no lag)
- ✓ Backed by a proven SPL focused company
- ✓ US based
- ✓ Hosted at professional SAS 70 audited locations
- ✓ Does not impose additional burden to your IT organization
- ✓ Includes infrastructure requirements
 - ✓ Backups
 - ✓ Failover
 - ✓ Data encryption
 - ✓ Update strategy
 - ✓ Software interoperability



Solutions Overview (continued)

■ Outsourcing (Continued)

- ✓ SaaS (Software as a Service)
- ✓ A “Unified Solution” that is.....
 - ✓ In production now
 - ✓ You could use today
 - ✓ Provides more value than just SPL compliance
 - ✓ A strategic tool for your organization
 - ✓ Low start up costs
 - ✓ Flexible
 - ✓ Based on your needs you can
 - ✓ Outsource fully
 - ✓ Use the application



SPL Portal Solution Demonstration



Questions and Answers



Thank you.

Craig Trautman – (813) 226-1863

ctroutman@intagras.com

Sean Lucey – (813) 226-1867

slucey@intagras.com